sentinelle MEDICAL

7. 510(k) Summary

APR 22 2010

510(k) Summary of Safety and Effectiveness for: Vanguard Breast MRI Auxiliary Table/Tabletop with 8/16 Channel Coil Array for GE 1.5T/3T MRI Systems

I. Manufacturer

Sentinelle Medical Inc.
555 Richmond Street West,
Suite 800,
Toronto, ON
Canada M5V 3B1

II. Contact Person

Joan Medley
Director, Regulatory and Quality
Tel: (647) 258-3607
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III. Product Name/Classification Name

Product Name:	Vanguard Breast 8/16 Channel, 1.5T/3T MRI Systems
Common Name:	Vanguard Breast MRI System
Classification Name:	Magnetic Resonance Imaging Accessory Class II as described in CFR 21 892.1075
Product Code:	MOS

IV. Date Prepared

March 25, 2010

V. Device Description

The **Vanguard Breast MRI Auxiliary Table/Tabletop with 8/16 Channel Coil Array for GE 1.5T/3T MRI Systems** is a receive-only MRI imaging coil and interventional system for the breast anatomy. The system consists of a table base and/or a tabletop. The tabletop supports the patient, the imaging coils and means for modest compression/immobilization of the breast, as well as a means of enabling interventional device guidance. The table base (optional) is used to support and transport the tabletop.

The tabletop, like other breast coils provides an aperture to admit the breasts. A corresponding aperture in the table base maximizes physician access to the breast(s) when the tabletop is at the home position. This table aperture is useful for guidance of interventional devices (such as biopsy needles), especially when it is desired to perform a biopsy from a medial approach.

The tabletop's compression system facilitates immobilization of the breast for imaging and interventional procedures and serves to hold the individual imaging coils in proximity to the breast(s).

Compression plates provided with the system are held in compression frames which may be positioned in the left-right and anterior-posterior directions and fixed in place to gently immobilize one or both breasts for interventional procedures.

When performing a stereotactic interventional procedure (such as biopsy or wire localization), one or more compression plates may be interchanged for a sterile, single use, disposable fenestrated plate cleared under FDA 510(k) number: K060873. The fenestrated plate has apertures that permit the physician to access the breast for intervention, while minimizing tissue motion.

When performing biopsy and/or imaging of a single breast, the system may be used with two compression plates immobilizing that breast. The contralateral breast support prevents the contralateral breast from interfering with medial-approach interventions.

When imaging both breasts, a medial coil element is used between the breasts in conjunction with two lateral coils. The tabletop's receive-only coil system acts to passively collect RF emissions from the nuclei excited by the MRI. The function of the tabletop is substantially equivalent to predicate devices used for breast MRI maging and intervention, including our legally marketed device 510(K) Number: K060873.

The Vanguard phased array coil set consists of 8 or 16 RF coil elements in a phased array design. The 16 channel coil array may be interchanged with a 10 or 2-channel coil array. The coil elements and electronics are enclosed in a rigid housing that is resistant to fluid ingress and is fire retardant. The coils are positioned close to the patient's breast during imaging. This receive-only coil is designed to give an improved signal-to-noise ratio, image resolution and image acquisition over that of a standard body coil.

The Sentinelle Vanguard Breast MRI Auxiliary Table/Tabletop with 8/16 Channel Coil Array for GE 1.5T/3T MRI Systems will consist of the following new models:

- ☐ Description: Sentinelle Vanguard Breast MRI Auxiliary Table/Tabletop, 3T, 16 Channels
  - o Model: 4000451
  - o Compatibility: General Electric Discovery MR750 3T
- ☐ Description: Sentinelle Vanguard Breast MRI Auxiliary Table/Tabletop, 1.5T, 16 Channels
  - o Model: 4000636

- Compatibility: General Electric Discovery MR450 1.5T and General Electric Optima MR450w 1.5T

☐ Description: Sentinelle Vanguard Breast MRI Auxiliary Table/Tabletop, 3T, 8 Channels

- Model: 4000700
- Compatibility: General Electric Signa HDxt 3T

☐ Description: Sentinelle Vanguard Breast MRI Auxiliary Table/Tabletop, 1.5T, 8 Channels

- Model: 4000198
- Compatibility: General Electric Signa 1.5T Systems

The various coil layout configurations (8/4/2 or 16/10/2) can be found in Appendix VIII.1.

A full description of the system in form and function and the accompanying technical drawings were provided in the Traditional 510(K) cleared in April 2006 under FDA 510(k) Number: K060873.

A representative copy of the Operator's Guide (User Manual) which details the proposed labeling (operating instructions, cautions, warnings, and indications for use) can be found in Appendix V.1.

VI. Intended Use

The Sentinelle Vanguard Breast MRI Auxiliary Table/Tabletop with 8/16 Channel Coil Array for GE 1.5T/3T MRI Systems is an open, receive only breast coil designed to provide magnetic resonance images of breast anatomy when used in conjunction with a Magnetic Resonance Scanner. These images can be interpreted by a trained physician. When used with a sterile plate, the device permits access to the breast anatomy for biopsy and localization procedures that can be performed by a trained physician.

*Note: The intended use of this modified device, as described in its labeling has not changed as a result of the modifications.

The benefits of the Vanguard 16Ch, receive-only coil includes:

- An increase in the Signal-to-Noise Ratio (improving image detail)
- A decrease in imaging acquisition time resulting from enhanced parallel imaging capability

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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Toronto, Ontario, M5V 3B1
CANADA

APR 22 2010

Re: K100113
Trade/Device Name: Vanguard Breast MRI Auxiliary Table/Tabletop with 8/16 channel coil array for GE 1.5T/3T MR Systems
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: March 25, 2010
Received: March 26, 2010

Dear Ms. Medley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **k100113**

Device Name: **Vanguard Breast MRI Auxiliary Table/Tabletop with 8/16 channel coil array for GE 1.5T/3T MR Systems**

Indications for Use:

The Sentinelle Vanguard Breast MRI Auxiliary Table/Tabletop with 8/16 Channel Coil Array for GE 1.5T/3T MRI Systems is designed to provide magnetic resonance images of breast anatomy when used in conjunction with a Magnetic Resonance Scanner. These images can be interpreted by a trained physician. When used with a sterile fenestrated plate, this device permits access to the breast anatomy for biopsy and localization procedures that can be performed by a trained physician.

Prescription Use ___x____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Robert L Becker Jr

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K100113